REMARKS

Claims 1, 2, 10-12 are pending. Claims 2, 10 and 11 have been amended. Claims 3-9 are withdrawn pursuant to a restriction requirement. Applicants expressly reserve the right to prosecute any withdrawn, canceled or deleted subject matter in other related patent applications. No new matter has been added.

Information Disclosure Statement

The Examiner has requested a copy of Reference A3 that was cited in the IDS filed July 27, 2006.

Reference A3 (11/346,580, filed February 2, 2006) is a reissue application of U.S. Patent 6,686,178, which was issued from U.S. Patent Application Serial No. 10/295,723, filed on November 15, 2002.

Specification

The examiner has requested that the trademarks Qiaquick, gluta Max-I, Fmax, Ficoll-Paque, RNeasy Midi, SuperscriptII, Pellet Paint, ElectroMax, Nucleobond-giga, Super Broth, and lipofectamine, etc. be capitalized wherever they appear and be accompanied by the generic terminology.

Please delete ~~Cytosensor~~ and insert at page 52, line 7,—microphysiometer CYTOSENSOR®-- .

Please delete ~~Qiaquick~~ and insert at page 71, lines 13, 22, 29; page 72, line 3; page 74, lines 19, 24; page 103, line 26; page 113, line 18, and --PCR purification reagents QIAQUICK®--.

Please delete ~~Qiagen Maxi Prep Kit~~ and insert at page 73, line 3; page 90, line 17; page 119, line 23--QIAGEN® Maxi Prep Kit--.

Please delete ~~Geneticin™~~ at page 73, line 13 and insert --G-418 Sulfate antibiotic GENETICIN™--.

Please delete ~~alamarblue~~ and insert at page 73, lines 18, 19; page 74, line 1; page 75, lines 12 , 21; page 76, lines 4, 15; page 77, line 27; page 83, line 18; page 99, line 14; page 109, lines 4, 5, 7; page 112, line 17; page 177, lines 8, 28; page 178, lines 11, 22 --cell growth and cytotoxicity indicator dye ALAMAR BLUE™--.

Please delete ~~gluta-Max-I~~ and insert at page 73, line 1, --cell media supplement L-GLUTAMAX-I® --.

Please delete ~~Fmax~~ and insert at page 74, line 4; page 76, line 17, page 99, line 15 --EMAX® microplate reader--.

Please delete ~~Ficoll-Paque~~ and insert at page 75, line 28; page 162, line 2 --tissue culture density media FICOLL-PAQUE PLUS™--.

Please delete ~~RNeasy-Midi~~ and insert at page 79, line 27 --total RNA isolation kit RNEASY® MIDI--.

Please delete ~~"MPG-mRNA purification kit"~~ and insert at page 79, line 29 --MPG®mRNA purification kit--.

Please delete ~~SuperscriptII~~ and insert at page 80, lines 10, 15--reverse transcriptase SUPERSCRIPT®II--.

Please delete ~~Pellet-Paint~~ and insert at page 81, lines 23, 30 --Non-fluorescent visible DNA co-precipitant PELLET PAINT®--

Please delete ~~DH10b-ElectroMax~~ and insert at page 72, line 11; page 75, line 1, page 83, line 4; page 85, line 30; page 113; page 26; --*E.coli* DH10b™ competent cells ELECTROMAX™ --.

Please delete ~~Nucleobond-giga~~ and insert at page 83, line 25 –an anion exchange matrix plasmid purification method NUCLEOTBOND®--.

Please delete ~~Super-Broth-II~~ and insert at page 84, lines 4, 9; page 86, line 2; page 134, lines 13, 15; page 135, lines 4, 6; page 172, lines 6, 9--enriched culture medium SUPER BROTH® II--.

Please delete ~~Qiaprep™~~ and insert at page 84, line 20 --QIAPREP®--.

Please delete ~~Lipofectamine~~ and insert at page 85, lines 3, 4, 6, 8, 9, 11; page 86, line 9; page 92, lines 12, 15, 16, 18, 19, 22, page 100; lines 4, 18; page 120, lines 2, 5, 8, 9, 12; page 123, line 8--transfection reagent LIPOFECTAMINE™--.

Please delete ~~QiaexII™~~and insert at page 87, line 20; page 108, line 24 --QIAEXII®--.

Please delete ~~Vectashield~~ and insert at page 101, line 16 --VECTASHIELD®--

Please delete ~~"RoboCycler Gradient 96"~~ and insert at page 101, line 30 --ROBOCYCLER® Gradient 96--.

Please delete ~~"RediLoad"~~ and insert at page 102, line 3 --REDILOAD™ agarose gel loading buffer--.

Please delete ~~Advantage~~ and insert at page 102, line 4--ADVANTAGE®--

Please delete ~~Marathon~~ and insert at page 103, lines 1, 2, 3, 5, 12, 13 --MARATHON®--

Please delete ~~Prime-It r RmT~~ and insert at page 106, line 9 –PRIME-IT®--

Please delete ~~ExpressHyb™~~ and insert at page 106, line 11; page 184, line 11 –EXPRESSHYB™--.

Please delete ~~Nycoprep~~ and insert at page 111, lines 26, 2; page 154, line 1 --NYCOPREP®--

Please delete ~~DH5α Library Efficiency~~ and insert at page 126, lines 29-30 –DH5α LIBRARY EFFICIENCY®--

Please delete ~~DH10Bac Max Efficiency~~ and insert at page 131, lines 11-12 --MAX EFFICIENCY® DH5B™--.

Please delete ~~FACSCalibur~~ and insert at page 144, line 22; page 154, line 21; page 186, line 11 --flow cytometer FACSCALIBUR™--.

Please delete ~~Cell-Dyn 3500~~ and insert at page 145, line 22; page 182, line 27 –CELL-DYN® 3500--.

Please delete ~~Instat~~ and insert at page 147 lines 19, 29; page 146, line 9--INSTAT™--.

Please delete ~~WinNonLin~~ and insert at page 152, line 1 --WINNONLIN®--.

Please delete ~~Dynabeads~~ and insert at page 151, line 14; page 154, line 29; page 155, line 12; page 156, line 21; page 157, line 5 --DYNABEADS®--

Please delete ~~RNeasy Miniprep~~ and insert at page 164, line 14 -- total RNA isolation kit RNEASY® MINI--.

Please delete ~~pBluescript II SK (+)~~ and insert at page 182, line 31–phagemid kit pBLUESCRIPT® II SK(+)--

The Examiner objected to the disclosure because it contains an embedded hyperlink and/or other form of browser-executable code (see p. 102).

Please amend page 101, lines 26-27 to delete:

~~A publicly available WWW server (http://shgc-www.standford.edu) allows chromosomal localization of markers~~.

Please amend page 102, line 17 to delete:

~~WWW server: http://cedar.genetics.soton.ac.uk/public_html/~~

Claim Objections

The Examiner objected to claim 2 as reciting unelected inventions.

Applicants have amended to claim 2 and deleted subject matter directed to unelected inventions. Applicants reserve the right to pursue the deleted subject matter in continuing prosecution.

The Examiner objected to claim 10 because the claim does not end with a period.

Applicants have amended claim 10 as requested by the Examiner.

Rejections Under 35 U.S.C. §112

The Examiner rejected claim 11 under 35 U.S.C. §112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants have amended claim 11 to correct the inadvertent omission of the term "the" so that the claim now recites "the sequence of amino acid residues".

Rejections Under 35 U.S.C. §112

The Examiner rejected claims 1, 2 and 10-12 under 35 U.S.C. §112, first paragraph, because the specification while enabling for fusion protein comprising a first polypeptide of SEQ ID NO: 2 or a first polypeptide comprising residues 32 to 162 of SEQ ID NO: 2, does not reasonably provide enablement for all possible fusion proteins comprising a first polypeptide of at least 90% or 95% identical to SEQ ID NO: 2 or

residues 32 to 162 of SEQ ID NO: 2 . The claims also recite the phrases "a sequence of amino acid" and thus, are broadly interpreted by the examiner as reading upon: (i) protein variants with any number of deletions, substitutions, or additions and (ii) fragments of SEQ ID NO:2, including sequences only 6 amino acids in length .

The examiner also rejected claims 1, 2 and 10-12 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants respectfully traverse the rejections. In making these rejections, the examiner has unreasonably interpreted the claims broadly as reading upon any and all DNA and protein variants with any number of deletions, substitutions or additions, and upon all fragments of SEQ ID NO: 2 provided those variants are at least 90% or 95% identical to SEQ ID NO: 2 and include sequences only 6 amino acids in length. Relying on the same broad interpretation, the examiner also rejected the same claims for failure to meet the written description requirement under 35 USC §112, first paragraph.

The USPTO must employ the "broadest reasonable interpretation" standard for examining claims where such broadest reasonable interpretation must be "consistent with the specification". (See, MPEP 2111). The key word in this standard is "reasonable". Applicants contend that the interpretation of the claims to encompass any number of variants and any fragment of 6 or more amino acid residues that is at least 90% or 95% identical to SEQ ID NO: 2 is not reasonable because it is not consistent with the use in the specification, that which was understood by those skilled in art, and the history of prosecution in family of patents from which this application arises.

The USPTO is unreasonably ignoring the recited sequence defined within the claim when interpreting the claim as reading upon "protein variants with any number of deletions, substitutions, or additions; and fragments of SEQ ID NO: 2, including sequences only 6 amino acids in length." The claims recite specific sequences, e.g. sequences with at least 90% or 95% identity residues 32-162 of SEQ ID NO: 2. This plain language, previously understood to mean what it says, a first polypeptide of a fusion protein will have at least 90% or 95% identity to a sequence comprising amino acid

residues 32-162 of SEQ ID NO: 2, has been essentially rewritten to mean: **a polypeptide of at least 90% (or 95%) identity to any six amino acids present in SEQ ID NO: 2.**

One consequence of interpreting the claims in this manner is that the longer the specified sequence is, the broader the claim actually is, which is not how claims are generally interpreted, nor how the claims were intended to be interpreted.

Moreover, Applicants contend that the USPTO's new interpretation of the contested claim language cannot be the "broadest reasonable interpretation consistent with the specification" and is consequently unreasonable because its interpretation manifestly ignores the context of the specification. The rejections under 35 USC §112, first paragraph, are based on the assertion the specification does not describe (written description) nor enable (enablement) variants, fragments or derivative polypeptides of SEQ ID NO:2. The examiner maintains that the specification merely invites one skilled in the art to further experiment because identification of the active site or binding site may not be sufficient to maintain activity. Applicants respectfully maintain that the examiner is incorrect in the assertions that applicants did not (1) provide teachings that provide guidance beyond just identifying a binding site, (2) attribute any function to the claimed protein, and (3) provide teachings for how to test for that function. The instant claims are directed to, and the specification discloses, functional polypeptides with at least 90% (or 95%) identity to the mature protein (residues 32-162). Additional fragments within SEQ ID NO:2, such as the complete helical region (residues 41-148), helix A defined as residues 41-56, helix B defined as residues 69-84, helix C defined as residues 92-105, and helix D defined as residues 135-148 of SEQ ID NO: 2 (See, table 1, page 13) are disclosed because these structural regions are known to be highly conserved within this cytokine family providing structural characterization that guide the skilled artisian to make changes within the sequence that maintain functional aspects of the protein. The specification discloses that detailed mutational analysis has been performed within this family and critical residues, not only the residues identified as binding residues, but also those involved in the helical and loop structures, have been identified (pages 10-13). Based on these studies, the effects of substitutions, deletions and additions are not merely speculation. Moreover, the biological function of polypeptides

of the present invention are clearly described in the specification and include: binding of the polypeptide to its binding partners (page 32, line 10), such as anti-zalpha11 ligand antibody or cognate receptor, a proliferative or differentiating activity; specialized cell functions (for example on page 34, lines 6-10). Numerous examples and assays describing *in vivo* and *in vitro* biological activites of the zalpha11 Ligand (a.k.a. IL-21) polypeptides of the present invention are provided. Explemary proteins are made and tested using the teachings and assays disclosed therein. Applicants assert that the examiner is incorrect in assuming that a skilled artisian would not know what function to test for. The specification identifies the cognate receptor, provides assays to test binding, including assays that measure biological activity, and therefore testing is routine experimentation. Applicants clearly describe the fragments and variants both structurally and functionally. Throughout, the specification describes and enables fragments of SEQ ID NO:2, sequences of varying lengths, and structural changes that can be made without compromising the function of the protein.

While the specification includes a generic description that polypeptides "of less than about 10 amino acid residues are commonly referred to as 'peptides'." (page 6, lines 19-21), the invention must be viewed in the context of the entire specification and claims. When viewed in this manner, it is clear that when the intent was to describe fragments, shorter sequences are defined as such. For example, when polypeptides are intended to encompass functional fragments , e.g., at least helix A, B, C, or D, or mature polypeptide sequences of SEQ ID NO:2, that information is clearly conveyed. When the intent is to cover a longer sequence, that sequence is recited. The specification offers clear description and enablement of specific fragments and variant sequences recited in the claims, and such sequences are identified based on scientific evidence and reasoning. Given a reasonable interpretation of the language consistent with the specification, claims directed to those specific sequences are clearly defined. The instant specification provides clear written support as well as sufficient disclosure and guidance for one of skill in the art to make and use the polypeptides of the present invention without undue experimentation, as required by 35 USC §112, first paragraph. Upon reading the specification and claims, those ordinarily skilled in the art would recognize that any

claimed polypeptides are biologically functional as stated within the specification (e.g., page 34, lines 5-6). Consequently, it would be unreasonable for a skilled artisan, or the USPTO, to read "a sequence of amino acid [residues] as shown in SEQ ID NO: 2 from residue 32 to residue 162", or residues 41-148 or residues 32-148, to include fragments as small as six amino acids as an element of the claimed invention.

To summarize applicants' position, the Office has adopted an unreasonable and overly broad interpretation for claims to a genus of polypeptides with at least 90% or 95% identity to a specific sequence of SEQ ID NO: 2. The Office has interpreted the claims to cover all polypeptides of at least six amino acids, with any substitution, deletion or addition. Applicants traverse the rejection of the claims because it based on an overly broad claim scope which has disregarded applicants' teachings, the actual data presented, and what would be considered a reasonable interpretation of the claim language. Applicants respectfully request the rejection be withdrawn and the claims be allowed.

Double Patenting

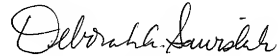
The Examiner provisionally rejected claims 1, 10 and 12 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 11/551,820 in view of Beckmann et al. (U.S. Patent No. 5,573,924).

Applicants will file a Terminal Disclaimer over claims 1-4 of copending Application No. 11/551,820, once the instant claims are deemed allowable. Applicants reserve the right to reconsider filing the Terminal Disclaimer should amendments to the claims be made such that the scope of the claims has changed.

Conclusion

In light of the above amendments and remarks, reconsideration and withdrawal of the rejections are respectfully requested. It is, thus, respectfully requested that claims 1, 2, and 10-12 are in condition for allowance and notification to that effect is respectfully requested. If for any reason the Examiner feels that a telephone conference would expedite prosecution of the application, the Examiner is invited to telephone the undersigned at (206) 442-6672.

Respectfully Submitted,



Deborah A. Sawislak
Registration No. 37,438

Enclosure:
Amendment Fee Transmittal (in duplicate)

Customer No. 10117
ZymoGenetics, Inc.
1201 Eastlake Avenue East
Seattle, WA 98102